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K011396

6.0 510(k) SUMMARY OF THE *IBD-CHEK*™ TEST

TECHLAB®, Inc. has evaluated the *IBD-CHEK*™ test, which is a new ELISA for the detection of elevated levels fecal lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The purpose of our study was to evaluate the performance of the *IBD-CHEK*™ test as an *in vitro* diagnostic aid for distinguishing active inflammatory bowel disease from active irritable bowel syndrome. Our results demonstrate the following:

- The test utilizes highly specific antibodies for human lactoferrin.
- When compared with microscopy in studies 1 and 2, the *IBD-CHEK*™ test had sensitivity and specificity results of 80.0% and 94.1%, and 90.0% and 51.7%, respectively. In the same studies, when compared with the *LEUKO*-TEST®, sensitivity and specificity results were 90.5% and 89.6%, and 86.4% and 57.5%, respectively.
- Clinical evaluations demonstrated that a positive result in the *IBD-CHEK*™ test exhibits a high correlation with clinically documented active inflammatory bowel disease. More than 86% of patients with active inflammatory bowel disease (ulcerative colitis and Crohn's disease) tested positive in the *IBD-CHEK*™ test. A negative result exhibits a high correlation with clinically documented active irritable bowel syndrome and healthy persons. The *IBD-CHEK*™ test showed predictive positive and predictive negative values of 100% and 87%, respectively and a correlation of 93%. All persons with active irritable bowel syndrome (100%) and all healthy persons (100%) tested negative in the *IBD-CHEK*™ test.
- The *IBD-CHEK*™ test can be completed within 75 minutes, providing the physician with reliable results.
- The absorbance value cut-off has been optimized to eliminate the need for an indeterminate zone, making test results simple to interpret.
- Based on these findings, we believe the *IBD-CHEK*™ test is substantially equivalent to other diagnostic tests now used to evaluate patients suspected of having inflammatory bowel disease. Further, our results demonstrate that the *IBD-CHEK*™ test is suitable as an *in vitro* diagnostic aid to help identify patients with active inflammatory bowel disease (IBD) and rule out those with active irritable bowel syndrome (IBS), which is noninflammatory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 8 2001

David M. Lyerly, Ph.D.
Vice President
TECHLAB, Inc.
1861 Pratt Drive, STE. 1030
Corporate Research Center
Blacksburg, VA 24060-6364

Re: 510(K) Number: K011396
Trade/Device Name: IBD-CHEK™
Regulation Number: 866.5570
Regulatory Class: I
Product Code: DEG
Dated: May 4, 2001
Received: May 7, 2001

Dear Dr. Lyerly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 STATEMENT OF INTENDED USE

510(k) Number (if known): K011396

Device Name: *IBD-CHEK™*

Indications For Use:

The *IBD-CHEK™* test is an ELISA for the qualitative detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation. The test can be used as an *in vitro* diagnostic aid to help identify patients with active inflammatory bowel disease (IBD) and rule out those with active irritable bowel syndrome (IBS), which is noninflammatory. FOR *IN VITRO* DIAGNOSTIC USE.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011396

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)